TAVR Using CoreValve

World experience and an update of the United States pivotal trial.

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It has been estimated that approximately 2% to 9% of patients older than 65 years have some form of aortic valve stenosis (or roughly 5 of every 10,000 people).[1,2] The prevalence is increasing due to our aging population,[3] and this number is expected to double over the next 20 years.[4,5] Estimates from the 2010 United States census suggest there are 40 million people over 65 years old. If 20% of the 1.6 to 2 million patients with aortic stenosis deemed to be critical received surgical intervention, cardiac surgeons would be extremely busy replacing valves.[6,7] However, this is not the case.

WHY SO FEW ARE BEING TREATED

There are an estimated 60,000 aortic valve replacements (AVR) performed in the United States each year,[8] significantly less than the 20% of those patients with aortic stenosis that you would anticipate a benefit from AVR. Charlson et al found that 65% of patients aged ≥ 60 years with severe aortic stenosis were not offered surgery as a treatment option, with age being cited as a common contrary indication, second only to comorbidities.[9] This finding is despite the fact that, when outcomes of surgical patients were compared with age-matched controls, patients who underwent AVR had life expectancies similar to those who did not have aortic stenosis.[10,11] Cardiologists were more likely than general internists to refer patients for AVR.[9]

A survey of the University of Michigan echocardiography database in 2005 found 159 patients who met the criteria for severe aortic stenosis.[12] Four patients were excluded from analysis for various reasons. Of 155 patients, 80 (52%) underwent AVR and 75 (48%) did not. Asymptomatic status was cited as the most common reason in the asymptomatic cohort, followed by medical contraindication. Yet, only one patient in that group underwent provocative stress testing to confirm a true asymptomatic status as opposed to a self-imposed reduction in general activities by patients to curtail symptoms.

Stress testing has been shown to be safe and uncovered many of those patients reported to be asymptomatic.[13] Among symptomatic patients, 30 (57%) for whom prohibitive operative risk was cited as the major rationale against AVR, calculated operative risk was < 5% in 11 (37%) and < 10% in 17 (57%); only six (35%) of these 17 were evaluated by a surgeon. Two of the more common risk calculators to predict surgical morbidity and mortality are The Society of Thoracic Surgery Calculator (STS) and the Logistic EuroSCORE. Although they have been shown to underestimate (STS)[14] and overestimate (EuroSCORE)[15] overall risk, they also fail to take into account several other contraindications, including liver disease, hostile mediastinum, previous chest wall radiation, or even extreme fragility. Stortecky and colleagues added a multidimensional geriatric assessment based on cognition, nutrition, mobility, activities of daily living, and frailty index in an attempt to better predict risk in older individuals undergoing TAVR.[16]

In symptomatic patients, in whom the predicted operative mortality and morbidity risk was thought to be prohibitive, the only viable option was percutaneous aortic balloon valvuloplasty (PABV). This changed in 2002 with the first-in-man report by Cribier et al describing a percutaneous aortic valve replacement (PAVR) approach in a 57-year-old man with critical aortic stenosis who was deemed to be inoperable due to significant comorbidities.[17] This ignited the development of several different devices,[18,19] resulting in rapid worldwide adoption. Patients with severe aortic stenosis now had a viable alternative to surgical AVR when deemed to be a prohibitive surgical risk.

The PARTNER (Placement of Aortic Transcatheter Valve) multicenter trial was the first to evaluate the safety and efficacy of percutaneous implantation of a balloon-expandable

aortic valve replacement. It consisted of two parallel individually powered trials: cohort A (high risk) included 699 patients randomized to PAVR versus surgical aortic valve repair,[20] and cohort B (inoperable) included 358 patients randomized to PABV medical therapy versus PAVR.[21] The widely publicized results showed the superiority of TAVR over medical (PABV) therapy in the inoperable cohort and equivalent or a noninferior mortality benefit at 1 year in the high-risk cohort. These exciting results were tempered by a slightly higher 30-day and 1-year stroke rate noted in the TAVR group (5.1% vs 2.4%; *P* = .07). At 2 years, the frequency of all neurological events (transient ischemic attacks and strokes) was higher with TAVR (11.2% vs 6.5%; *P* = .05). However, with 12 additional strokes in the surgical cohort and eight in the TAVR cohort, the 2-year overall stroke rate is reaching equipoise between the groups (hazard ratio, 1.22; 95% confidence interval, 0.67–2.23; *P* = .52).[22]

THE COREVALVE REVALVING SYSTEM

The CoreValve revalving system (Medtronic, Inc., Minneapolis, MN) is made up of three different components: a trileaflet porcine pericardial tissue valve attached to a self-expanding nitinol support frame, delivered on an 18-F AccuTrak delivery catheter (Medtronic, Inc.). The CoreValve device was originally available in 26-mm and 29-mm valve systems, which could be placed in patients with an annulus 21 to 23 mm and 23 to 27 mm, respectively. Valves measuring 31 mm and 23 mm were recently introduced for those patients with larger (26–29 mm) and smaller (18–20 mm) annular dimensions, allowing the CoreValve revalving system to be used in annulus perimeters from 56.5 to 91.1 mm.

The nitinol frame is broken up into four different zones (Figure 1). The inflow portion of the frame exerts high radial force and elasticity to secure the frame in an often noncircular annulus while maximizing conformation and sealing to prevent perivalvular leaks and migration. The mid-frame is designed to resist deformation and preserve optimal geometry and leaflet coaptation. It is also concave in design to maintain coronary perfusion and able to accommodate up to an 8-F catheter to access the coronary ostia (Figure 2). Gross examination of four autopsy specimens, the implant dates of which ranged from 3 days to 350 days, showed neointimal tissue covering most of the frame struts in contact with the aortic wall, but areas of high-velocity blood flow were bare.[23] The upper and largest part of the frame comprises the outflow portion, which exerts low radial force to accommodate anatomic variations and orient the valve to the aortic root to optimize flow. The trileaflet valve and skirt is constructed from six individual pieces of porcine pericardium, believed to provide a lower profile when compared to bovine pericardium. The valve has been extensively bench tested to 200 million cycles (or 5 years) for the tissue component and 600 million cycles (or 15 years) for the frame, which is consistent with surgical valves.[24] Clinically, at 1 year after implantation, cine imaging failed to identify fractures or abnormalities in frame integrity.[25]

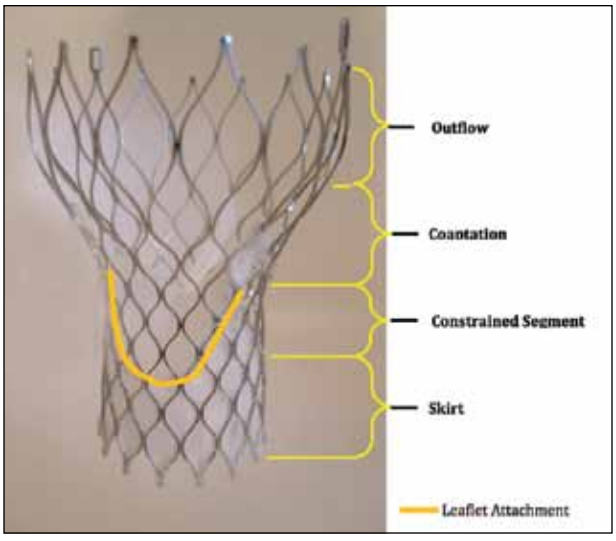

Figure 1. The CoreValve revalving system. Pericardial tissue valve attached to a self-expanding nitinol support frame. The frame has four distinct zones.

Peripheral vascular disease, along with aortic stenosis, is a disease of the elderly, and it can be difficult to advance larger-caliber sheaths from a transfemoral access in patients who have both. The 18-F AccuTrak delivery catheter allows for alternative access via the subclavian, axillary, and direct aortic routes via ministernotomy or minithoracotomy in patients in whom transfemoral access is not feasible.

In the Italian National Registry of 514 consecutive patients at 13 Italian hospitals, 54 patients who had unfavorable iliofemoral anatomy or extensive disease were accessed via the subclavian or axillary approach. No specific complications for the subclavian access (vessel rupture, vertebral or internal mammary ischemia) were reported. Thirty-day mortality was 0% versus 6.1% in the subclavian versus femoral groups, respectively (*P* = .13).[26] A true percutaneous option was reported in 24 high-risk patients, utilizing the ProStar XL (Abbott Vascular, Santa Clara, CA) or two ProGlide devices (Abbott Vascular) in a preclose method confirming the feasibility and safety of this approach.[27] Direct aortic access has also gained favor in patients in whom both femoral and subclavian access is not available. In 19 European centers between June 2008 and the end of 2011, 115 direct aortic access implantations were performed. Procedural success was 98%, with a

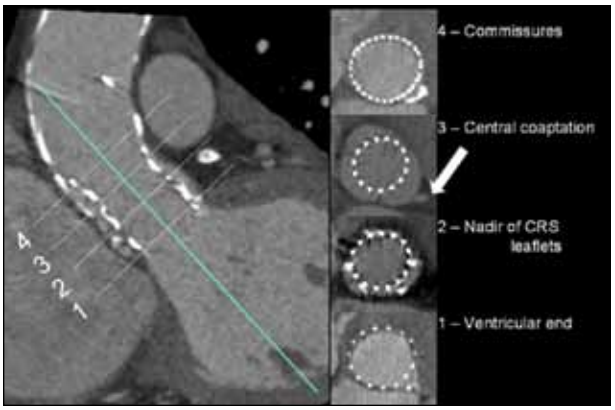

Figure 2. CTA imaging after CoreValve implantation. Zones 1 and 4 show good apposition to the annulus and ascending aorta, respectively. Zone 2 shows the leaflet level. Zone 3 shows the mid-sinus of Valsalva to allow coronary perfusion. The left main can be seen in the lower right (white arrow). Reprinted from Am Coll Cardiol, Vol. 54, Schultz CJ, Weustink A, Piazza N, et al. Geometry and degree of apposition of the CoreValve revalving system with multislice computed tomography after implantation in patients with aortic stenosis, 911–911, 2009. Reprinted with permission from Elsevier.

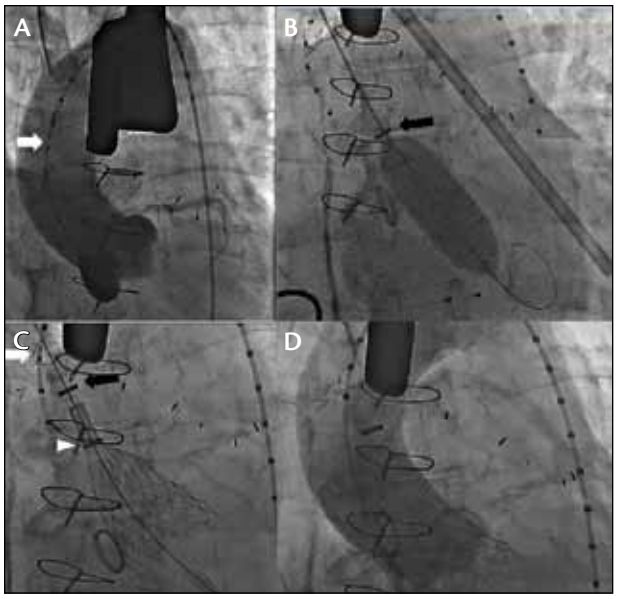

Figure 3. Direct aortic access for CoreValve implantation. Angiography of the ascending aorta (A, white arrow denotes a graft marker that was placed at the direct access site). Valvuloplasty balloon fully inflated (B, black arrow denotes the end of the access sheath). Partially deployed CoreValve (C, notice the access point [white arrow], sheath end [black arrow], and the delivery catheter [arrow point] all seen at the time of deployment). Deployed CoreValve (D).

30-day mortality of 9.7%. A learning curve was identified for this approach. The average mortality rate for a center's first three cases was 14% versus 7% for all subsequent cases. In cases completed before 2011, the mortality rate was 15%, but in 2011, the mortality rate decreased to 8.2%.[28] The direct aortic approach offers some distinct advantages pertaining to the delivery of the valve (ie, the ability to control the sheath and delivery catheter close to the point of insertion and release) (Figure 3).

Early Experience and Patient Selection

The CoreValve revalving system has been successfully used in more than 10,000 patients worldwide who were determined to be at high or extreme risk for conventional AVR. Many questions still exist about which patients will experience long-term benefit. Of equal importance is risk stratification, or the ability to determine which patients are most likely to experience complications as a result of the implant,[29] or which will receive little or no benefit from TAVR.

Early/Registry Experience

Multiple single-center reports are available on the benefits of the CoreValve revalving system. To date, the vast majority of clinical experience with the CoreValve system is gleaned from multiple national registry reports,[30-37] despite the inherent issues associated with registries (ie, different patient selection process, endpoints not uniformly or blindly adjudicated, even different definitions for events). However, registries do provide insight regarding the effectiveness of and potential complications with the CoreValve revalving system. The national registries reported comprise 2,352 patients, with an average age of 80.9 ± 1.4, a EuroSCORE of 19.7 ± 3.4, and a mean gradient of 43.4 ± 1.34. Thirty-day mortality ranged from 2.2% to 15.2%, and the 1-year mortality rate ranged from 15% to 21.7%. Several registries used 6-month or 2-year endpoints. Pacemaker rates ranged from 19.1% to 42.5%, and stroke rates ranged from 2.2% to 4.5%. Many of these registries did not use the currently accepted Valve Academic Research Consortium (VARC) endpoint definitions.

The VARC was introduced to standardize endpoints of mortality, myocardial infarction, stroke, bleeding, acute kidney injury, vascular complications, and prosthetic valve performance. Composite endpoints for TAVR safety and effectiveness were also recommended in this report.[38] A recent meta-analysis of 3,519 patients reported in 16 studies using the VARC definitions of major outcomes revealed a 92.1% device success rate. The all-cause, 30-day mortality was 7.8%, with a major vascular complication rate of 11.9%, and a major stroke rate of 3.2%. A new permanent pacemaker placement rate was 13.9%, which is signifi-

cantly higher when using the CoreValve (28.9%) versus the Sapien valve (4.9%) (Edwards Lifesciences, Irvine, CA).[39]

THE ADVANCE TRIAL

The ADVANCE trial, which was recently reported at EuroPCR, studied 1,015 "real-world" patients who were enrolled from March 2010 to July 2011, in 44 centers from 12 countries in Western Europe, Asia, and South America.[40] All centers had conducted at least 40 TAVR procedures prior to the study and had a heart team in place. Clinical endpoints were reported according to VARC definitions. All primary endpoint/events were adjudicated by an independent clinical events committee. An independent neurologist adjudicated all cerebrovascular events utilizing all available relevant source documents, including neuroimaging and systematic NIH Stroke Scale assessments.

The primary endpoint was major adverse cardiac and cerebrovascular events (MACCE) at 30 days after the procedure, defined as a composite of all-cause mortality, myocardial infarction (Q-wave and non-Q-wave), emergent cardiac surgery or percutaneous reintervention, and stroke. The average gradients were reduced from 45.6 mm Hg to 9.5 mm Hg, with an improvement in valve area from 0.7 cm^2 to 1.7 cm^2 at 6 months. Overall, MACCE was 8.3%, and all-cause mortality was 4.5%. Major and minor stroke were 1.2% and 1.7%, respectively. New pacemaker implantation rates varied between centers, ranging from 15% to 39% ($P = .031$). There was no mortality difference between patients who required a permanent pacemaker as a result of TAVR and those who did not.[40]

The ADVANCE trial also noted a low overall stroke rate of 2.9%, but female patients had a higher rate of neurological events (4.4% vs 1.4%; $P < .01$), and these tended to be more minor strokes. The vascular event rate was also higher in female patients (14.1% vs 7.1%; $P < .01$). Female patients who were also significantly older (82.2 years vs 79.9 years; $P < .001$) had higher mean/peak gradients (47.6 mm Hg and 79 mm Hg vs 43.5 mm Hg and 72.5 mm Hg, respectively; $P < .001$) and were prescribed fewer cardiovascular medications.[41]

The Current United States Pivotal Trial

There are currently 43 centers across the United States that are actively recruiting patients into the United States pivotal CoreValve trial. Critical aortic stenosis definition is based on the American Society of Echocardiography criteria of a mean gradient of ≥ 40 mm Hg, or a mean velocity of ≥ 4 m/s and a valve area of 0.8 cm^2 or a valve index of 0.5 cm^2/m^2. A transaortic gradient of 40 mm Hg at the time of catheterization is also is accepted. Annular sizing to determine valve size, aortic root/LV angle, and access vessels (iliac and subclavian) are evaluated by CTA. The trial consists of two arms. The extreme-risk arm is defined as patients who are determined to have a surgical risk based on STS score and incidental finding as stated previously, such as fragility, liver disease, etc., with a predicted operative mortality or serious, irreversible morbidity that exceeds a 50% 30-day mortality. Patients who qualify progress to stent valve implantation. The second arm (high surgical risk) is defined as patients whose operative mortality is ≥ 15% or in whom there is a serious, irreversible morbidity risk of < 50% at 30 days. Those that qualify are randomized 1:1 to open surgical replacement versus TAVR.

Primary endpoints in the extreme cohort include all-cause death or major stroke at 12 months (compared to performance goals). The primary endpoint in the high-risk cohort is all-cause mortality. The secondary end points of both cohorts reflect safety concerns, such as the individual and composite endpoints of death, MI, stroke and reintervention, need for a pacemaker, and rehospitalizations, and efficacy parameters, such as change in NYHA class, 6-minute walk test improvement, and quality-of-life evaluations, etc. The extreme-risk cohort is complete, with the last patient being enrolled and treated early in 2012. Patients with extreme-risk aortic stenosis can still be enrolled in the study in a continued access format, and the data continue to be collected and analyzed. The high-risk cohort continues to enroll and is on target to be completed late summer 2012. A neurological substudy has been initiated to evaluate patients by a neurological team before and after aortic valve intervention in both surgical and percutaneous arms.

Other Areas of Investigation

SURTAVI. SURTAVI is designed to compare TAVR utilizing the CoreValve revalving system to standard surgical replacement in the intermediate-risk population.

Valve-in-valve. As wider indications are being explored, failing pre-existing valves or endoprostheses appear to be a logical extension. Multiple cases have been reported utilizing the CoreValve for a failing Sapien valve or surgically implanted bioprosthesis.[42-44] The use of a Sapien valve for failing CoreValve has also been reported.[45] These small numbers will need to be evaluated in larger randomized trials to determine safety and efficacy of this strategy. These reports show that it is feasible.

Multivalve pathology. Patients with isolated aortic stenosis are the purview of the CoreValve pivotal trial and PARTNER trial, yet many patients present with aortic stenosis and other valve pathology, such as mitral regurgitation (MR) or tricuspid regurgitation. Toggweiler and associates reviewed 451 patients with aortic stenosis

from two Canadian centers who were undergoing TAVR and who also had varying degrees of MR (from mild to severe). Those patients with moderate or severe MR in association with TAVR had a higher early mortality but similar late mortality. MR was reduced in 55% of those patients with moderate or severe MR, most notably in those with functional MR, high transaortic gradients, in sinus rhythm, and normal pulmonary pressures.[46]

Although there are more than enough questions that need to be answered in the extreme-, high-, and intermediate-risk patients undergoing TAVR, there is no doubt that as this technology matures, there will be other areas in which TAVR will need to be evaluated. Some other areas where TAVR may have a role include low-risk patients, an association with coronary bypass, and in association with transcatheter options for other valves (ie, MitraClip, Abbott Vascular).

CONCLUSION

Therapies for aortic stenosis will continue to evolve. The gold standard, open surgical replacement, will remain in the forefront for many years as transcatheter therapies mature. Although the current data do not support a mortality advantage of TAVR over standard open replacement in the high-risk cohort, the perceived less-invasive nature of the procedure may result in more patients who are referred for evaluation and possible treatment of critical aortic stenosis. ■

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